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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,096	12/27/2004	Philippe Msika	065691-0381	9007
22428 7590 03/05/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
WINTERBERG, NISSA M				
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03/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,096

Applicant(s)

MSIKA ET AL.

Examiner

Nissa M. Westerberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 22, 25 - 37 is/are pending in the application.
- 4a) Of the above claim(s) 27 - 30, 32, 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 25, 26, 31, 34 - 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed December 13, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 20, 22 and 25 – 37 are pending. Claims 27 – 30, 32 and 33 are withdrawn as not being drawn to the elected invention. Claims 20, 22, 25, 26, 31 and 34 – 37 are currently under examination.

Claim Rejections - 35 USC § 102

1. Claims 20 – 26 were rejected under 35 U.S.C. 102(b) as being anticipated by EP 0829261). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 14, 2007 and those stated below.

Applicant's traverse this rejection because the reference teaches percutaneous administration and not topical application to the skin and that the publication does not provide and suggestion or motivation to apply one or more isoflavones in an aglycone or glycosylated form.

These arguments have been fully considered but they are not persuasive.

In the dictionary.com definition of percutaneous (accessed 2/13/08), the definition from the Random House unabridged dictionary (p 2) states that percutaneous means "administered, removed or absorbed by way of the skin". In light of this definition, Applicant's allegation that an obvious typographical error in the prior art of equating percutaneous administration as being onto skin and that "onto" should really be "through" is not found persuasive. One way in which application through the skin can be accomplished is by application of a product onto the skin. When the compositions of the instant application are applied topically to the skin, the site of action is not on the exterior of the skin but rather through the skin layer to where the fat cells are located. The medical definition of topical from dictionary.com (accessed 2/13/08) defines the term topical to mean as applied externally to a particular part of the body (p 1, definition 4) such as a topical anesthetic. Thus, the composition is topically applied and is absorbed by way of the skin (percutaneous administration) to the cells where the active ingredients exert their effect (fat cells for the instant application, nerve cells for the topical anesthetic).

The compositions in '261 only contain one isoflavone and one isoflavone is an embodiment in the claims of the instant application. Genistein and daidzein are both aglycones while genistin and daidzin are both glycosylated forms. Suggestion and/or motivation to combine more than one isoflavone in the composition to promote slimming or localized excess are not relevant as these claims are being rejected under 35 U.S.C. 102 and not under 35 U.S.C. 103.

Claim Rejections - 35 USC § 103

2. Claim 31 was rejected under 35 U.S.C. 103(a) as being unpatentable over EP '261 in view of Di Pierro (PGPub 2004/0151786) and Mazur et al (1998, Nutritional Biochemistry). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 14, 2007 and those stated below.

Applicant traverse the argument that neither Di Pierro nor Mazur et al. cure the deficiencies of '261 reference. This rejection is also traversed on the grounds that the extract taught in Mazur et al. is an extract of *Sophora japonica* seeds and not the *Sophora japonica* flowers of the claims of the instant application.

These arguments have been fully considered but they are not persuasive.

As discussed above, the '261 reference does teach application to the skin surface in a topical manner of the composition that exerts a slimming effect. It is also noted that as written, this claim does not require the presence of all the ingredients listed, although combinations of the ingredients are explicitly mentioned.

While the starting material for the extract is not the same in Mazur et al. and the claims of the instant application, Applicant does not define the process used to obtain the extract or the components present in the extract but merely states some of the ingredients that this extract is rich in (p 11, ln 12 – 17). Applicant has not presented any evidence that the ingredients of the flower extract are not present in an extract obtained

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from the *Sophora japonica* seeds in the method described by Mazur et al. Without factual support, this argument is a mere allegation and is not found to be persuasive.

New Claim Objections

4. Claim 37 is objected to because of the following informalities: the Latin name for the last species is not found in the specification nor can the Examiner find any indication as to the existence of the species "*Entomorpha compressa*". To further prosecution of this application, the Examiner has assumed that a typographical error has been made in this claim and that the correct Latin name is "*Enteromorpha compressa*" as disclosed in the specification. Appropriate correction is required.

New Claim Rejections - 35 USC § 103

5. Claims 34 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '261.

As discussed above, '261 discloses the use of compositions with one isoflavone such as genistein. The prior art does disclose that when used in a form for oral or percutaneous administration, the isoflavone compound is present in an amount of 5 – 1,000 mg/mL ('261, p 2, ln 31 – 33) but does not disclose the amount of the ingredient in weight percent as in the claims of the instant application. Since the density of the

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composition in '261 is not given, the amount of active ingredient in mg/mL cannot be accurately determined as a weight percent.

For a composition whose density is around that of water (1 g/mL), a concentration of 5 mg/mL would be a composition that contains 0.5% isoflavone by weight, which overlaps with the ranges of 0.01% to 10% by weight, 0.1 to 3% by weight and 0.0085% to 8.5% claimed by Applicant. Even if the density of the actual composition prepared differs from that used in the estimation above, the ranges presented in the claims of the instant application included that value and extend to both higher and lower percentages. Thus, the general condition of the claim is disclosed in the prior art. The amount of the active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of active ingredient in the composition in order to best achieve the desired results.

Therefore, the disclosure of an approximate amount of the isoflavone active ingredient in the composition renders obvious the weight percent ranges of the isoflavone active ingredient of the instant application to one of ordinary skill in the art at the time of the instant invention.

6. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '261 in view of Di Pierro and Mazur et al. as applied to claim 31 further in view of Zulli et al. (PGPub 2002/0160064).

As discussed above and in the Office Action mailed on September 14, 2007, the combination of '261, Di Pierro and Mazur et al. teach a combination of isoflavones, *Centelle asiatica* extract and *Sophora japonica* extract that can be used in a method to promote slimming or fighting localized excess weight. None of these references mentions *Enteromorpha compressa* in such compositions.

Zulli et al. discloses cosmetic compositions comprising aglycone isoflavones (paragraph [0014]) that can further comprise at least one algal extract (paragraph [0017]). Zulli et al. discloses that extracts of algal are becoming an important source of raw material in cosmetic compositions and that these extracts contain a wide variety of ingredients (paragraph [0021]). These extracts are effective in treating cellulitis in part because of their lipolytic (lipid (fat) degrading) activity (paragraph [0021]).

While Zulli et al. does not appreciate that isoflavones can be used in promote slimming or fight localized excess weight, the use of isoflavones for that purpose is taught in EP '261. Zulli et al. does disclose that algal extracts possess fat hydrolysis activity, that would be useful in a method of promoting slimming and/or fighting localized excess weight. *Enteromorpha compressa* is a green marine alga (as evidenced by the Aluka entry for *Enteromorpha compressa*, accessed 2/13/08) and while this species of alga is not exemplified in Zulli et al., one of ordinary skill in the art would have a reasonable expectation of success to use an extract from this particular algal species in

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combination with an aglycone in making a composition that can be used to treat a variety of conditions such as skin aging and to promote slimming or fighting localized excess weight.

Given the teachings of Zulli et al. as to compositions comprising an isoflavone and an algal extract, one of ordinary skill would conclude, in light of the teachings of EP '261, that this composition could also be used in a method for promoting slimming and/or fighting localized excess weight. In combination with Di Pierro and Mazur et al., the idea to combine these ingredients flows logically from their having been individually taught in the prior art (see *In re Kerkhoven*). Therefore, it would have been obvious to one of ordinary skill in the art to use a composition comprising at least one isoflavone and extracts from *Sophora japonica*, *Centelle asiatica* and the alga *Enteromorpha compressa*.

Conclusion

Claims 20, 22, 25, 26, 31 and 34 – 37 are rejected. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. This application contains claims 27 – 30, 32 and 33 drawn to an invention nonelected with traverse in the reply filed on August 20, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW